

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Rodriguez et al. )  
 ) Group Art Unit: 1614  
Attorney Docket No.: 31140-B )  
 )  
Filed: January 18, 2002 )  
 )  
For: Prevention of Ovarian Cancer by )  
Administration of a Vitamin D Compound )  
 )

**PRELIMINARY AMENDMENT**

Dear Sir:

Applicants submit the following preliminary amendment to this application, which is a continuation of application serial no. 09/479,837, which is a continuation of application serial no. 08/073,010, now issued as U.S. Patent No. 6,034,074 which is a continuation in part of 08/713,834 now issued as U.S. Patent No. 6,028,064.

**AMENDMENTS**

**IN THE SPECIFICATION**

At page 1, line 6, delete "This application" and insert therefor:

-- This application is a continuation of copending application 09/479,837, which is a continuation of application Ser. No. 08/873,010, filed on June 11, 1997, now issued as U.S. Patent No. 6,034,074, which--

At page 1, line 7, after "1996" insert:

--, now issued as U.S. Patent No. 6,028,064--

## IN THE CLAIMS

Please cancel claims 1-34.

Please add the following new claims:

--35. A pharmaceutical composition comprising a Vitamin D compound and a hormone product in a single unit dosage.--

--36. The pharmaceutical composition of claim 35 wherein said hormone is a progestin product.--

--37. The pharmaceutical composition of claim 36 wherein the Vitamin D compound is present at a dosage equivalent of from 0.0001 to 1.0 mg 1,25-dihydroxyvitamin D<sub>3</sub>/kg of body weight and wherein the progestin product is present at a dosage less than or equal to a dosage equivalent to 10.0 mg of norethindrone.--

--38. The pharmaceutical composition of claim 37 wherein the Vitamin D compound is present at a dosage equivalent of from 0.005 to 0.1 mg. 1,25-dihydroxyvitamin D<sub>3</sub>/kg of body weight and wherein the progestin product is present at a dosage less than or equal to a dosage equivalent to 1.0 mg of norethindrone.--

--39. The pharmaceutical composition in claim 35 wherein said hormone product is selected from the group consisting of estrogens and progestins.--

--40. The pharmaceutical composition in claim 35 wherein said hormone product compound comprises estrogen.--

--41. The pharmaceutical composition of claim 40 wherein the Vitamin D compound is present at a dosage equivalent of from 0.0001 to 1.0 mg 1,25-dihydroxyvitamin D<sub>3</sub>/kg of body weight.--

--42. The pharmaceutical composition of claim 41 wherein the Vitamin D compound is present at a dosage equivalent of from 0.005 to 0.1 mg. 1,25-dihydroxyvitamin D<sub>3</sub>/kg of body weight.--

--43. The composition of claim 36 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.--

--44. The composition of claim 40 wherein such estrogen is conjugated equine estrogen.--

--45. A contraceptive regimen comprising compositions including a Vitamin D compound and a hormone product.--

--46. The regimen of claim 45 wherein said hormone product includes a progestin product.--

--47. The regimen of claim 46 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.--

--48. The regimen of claim 47 wherein said progestin is levonorgestrel.--

--49. The regimen of claim 46 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.--

--50. The regimen of claim 45 wherein said hormone product includes a estrogen product.--

--51. The regimen of claim 50 including a composition wherein Vitamin D compound and said estrogen are present in a single unit dosage.--

--52. The regimen of claim 50 further including a progestin.--

--53. The regimen of claim 52 wherein said Vitamin D compound, said progestin and said estrogen are present in a single unit dosage.--

--54. The regimen of claim 53 wherein said progestin is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.--

--55. A hormone replacement therapy regimen for administration to a post-menopausal woman comprising compositions including Vitamin D compound and a hormone product.--

--56. The regimen of claim 55 wherein said hormone product includes a progestin product.--

--57. The regimen of claim 56 wherein said progestin product is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.--

--58. The regimen of claim 57 wherein said progestin is levonorgestrel.--

--59. The regimen of claim 56 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.--

--60. The regimen of claim 55 wherein said hormone product includes a estrogen product.--

--61. The regimen of claim 60 including a composition wherein Vitamin D compound and said progestin are present in a single unit dosage.--

--62. The regimen of claim 60 further including a progestin.--

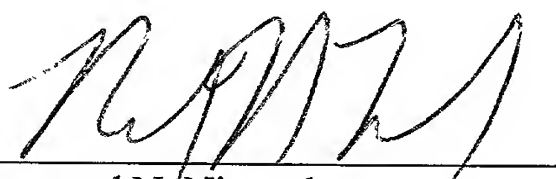
--63. The regimen of claim 62 wherein said Vitamin D compound, said progestin and said estrogen are present in a single unit dosage.--

--64. The regimen of claim 63 wherein said progestin is a derivative of 17-alpha-hydroxy-progesterone or 19-nortestosterone.--

#### **REMARKS**

Applicants request allowance of new claims 35-64.

Respectfully submitted,



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